GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2992
ANSWERED ON:13.08.2003
REGULATORY STANDARDS ON MEDICAL DEVICES
M. JAGANNATH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Union Government have any proposal to apply regulatory standards on the medical devices manufactured by various manufacturing units across the country;

(b) if so, the details thereof;

(c) whether the proposed standards would also be made applicable to the medical equipment being imported; and

(d) if so, the details thereof?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a)&(b): There is no regulatory standards for all medical devices. However, the following medical devices are regulated under the provision of Drug & Cosmetics Act, 1940 and Rules thereunder.

1. Sterile disposable perfusion sets.
2. Sterile disposable hypodermic syringes.
3. Sterile disposable needles.
4. In vitro diagnostic devices for HIV, HbsAg and HCV
5. Mechanical contraceptives (condom, CuT and Tubal rings.)
6. Sutures.

The standards for medical devices are prescribed by Bureau of Indian Standard, which are advisory in nature.Formulation of standards are through a well defined procedure by a regular Committee comprising of various interest groups as per provisions under Bureau of Indian Standards Act, 1986 and amendments from time to time. This is an ongoing process.

(c)&(d): The items mentioned above, if imported will be regulated under the said Act. However, imported medical equipments for government institutions are procured after evaluation in terms of the efficacy, utility and price by Technical Committee comprising of concerned experts, after observing the codal formalities.